UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

NICHOLAS SKIADAS, Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. ACER THERAPEUTICS INC., CHRIS SCHELLING, and HARRY PALMIN, Defendants.	**CASE No.: 1:19-cv-06137-GHW** **SECOND AMENDED CLASS ACTION COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS** **CLASS ACTION**

Lead Plaintiff Nicholas Skiadas ("Plaintiff"), by Plaintiff's undersigned attorneys, individually and on behalf of all other persons similarly situated, alleges the following based upon personal knowledge as to Plaintiff's own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiff's attorneys that included, among other things, reviewing Defendants' public documents, conference calls, and public announcements, the United States Securities and Exchange Commission ("SEC") filings of Acer Therapeutics Inc. ("Acer" or "Company"), wire and press releases, and other information readily obtainable on the Internet. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal securities class action brought on behalf of a class consisting of all persons and entities, other than Defendants[1] and their affiliates, who purchased or otherwise acquired the securities of Acer from December 12, 2017 through June 24, 2019, both dates

[1] The Defendants include: Acer; its president and chief executive officer ("CEO"), Chris Schelling ("Schelling"); and its chief financial officer ("CFO"), Harry Palmin ("Palmin").

inclusive ("Class Period"). Plaintiff pursues remedies against Acer and certain of its officers and directors for violations of federal securities laws.

2. Acer is a development-stage pharmaceutical company that touts itself as focusing on "the acquisition, development, and commercialization of therapies for serious rare and life-threatening diseases with significant unmet medical needs."

3. This case concerns Acer's effort to commercialize celiprolol, a drug in the beta-blocker class, in the United States under the trademark "EDSIVO" for the treatment of a rare genetic disorder known as vascular Ehlers-Danlos Syndrome ("vEDS"). The Company devoted well over 80% of its research and development expenses to EDSIVO since it was founded in 2013.

4. Celiprolol has not been approved for any indication in the United States, but has been approved for the treatment of hypertension in the European Union since 1984 and is available there as a low-cost generic drug. Celiprolol is not approved for use in vEDS patients in Europe, but is prescribed off-label[2] to vEDS patients there. Although celiprolol is not approved by the FDA, patients can be import it for personal use, including through online pharmacies. Other, similar beta-blockers, that are available as low cost generics, are used to treat vEDS patients in the United States.

5. Instead of sponsoring its own clinical trial to test the efficiency of celiprolol on vEDS patients, Acer purchased an old study from France, published in 2010, which consisted of only 53 patients (the "Ong Trial"). The Ong Trial was the center piece of the New Drug Application ("NDA") that Acer submitted to the Food and Drug Administration ("FDA") for EDSIVO.

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[2] A drug is prescribed off-label when a doctor prescribes it for a condition that a government drug regulatory agency did not approve it for. A drug's manufacturer cannot market a drug for off-label use, but doctors are not limited to writing prescriptions for approved indications.

6. The FDA has a program to encourage research into treatments for rare diseases that grants seven years of marketing exclusivity for drugs intended to treat a rare condition, which are known as "orphan drugs." Acer had no intention of conducting any new clinical research or trials or generating any original data on celiprolol for its EDSIVO NDA. Instead, Acer only confirmed the existing data by conducting a "retrospective source verified analysis" of the Ong Trial. Additionally, celiprolol is available as a cheap generic drug in Europe. Nevertheless, according to analysts, Acer intended to use the FDA rules meant to encourage funding research into drugs for rare diseases to gain market exclusivity that would allow Acer to charge vEDS patients more than $100,000 a year for EDSIVO.

7. Less than a year after acquiring the rights to the Ong Trial data, Acer became a public company through a reverse merger in September 2017 and needed to raise a significant amount of money to continue as a going concern.

8. In the prospectus supplement for its December 2017 offering, Acer claimed that "***the FDA agreed that additional clinical development is not needed***" for EDSIVO (emphasis added). Acer made similar statements about the FDA's view of the Ong Trial in its 2017 Form 10-K and its prospectus supplement for another secondary offering that it completed in August 2018. On the strength of its representations that the FDA would approve EDSIVO based on the Ong Trial Data, the Company raised gross proceeds of $12.56 million from its December 2017 offering and $46.0 million in gross proceeds from its August 2018 offering.

9. Acer's representation that the FDA had agreed that no additional clinical development was needed was extremely important to investor confidence that EDSIVO would be approved because of the weakness of the data from the Ong Trial. Although, Defendants falsely stated that the Ong Trial was a "robust clinical study" and it had "achieved statistical significance,"

it had numerous flaws that would have been quickly recognized by the FDA as a "red flag" or serious impediments to FDA approval. In addition to the fact that the Ong Trial only had 53 participants, it was discovered during the study that ***20 of the 53 participants*** did not have the mutation that causes vEDS. Furthermore, there was a severe imbalance between the study's experimental and control arms with respect to the number of patients confirmed as suffering from vEDS. While only 52% of the 25 patients in the experimental arm were confirmed to have vEDS, 71% of the 28 patients in the control group were confirmed as having the genetic mutation. Because of the imbalance between the experimental arm and the control group, there was a clear-cut bias in the Ong Trial towards a finding of a treatment benefit for the group of patients taking celiprolol. Additionally, because of the small number of participants in the study and even smaller number of participants who had the mutation, there was an insufficient sample size (the trial was "underpowered") to test a clinically realistic advantage that celiprolol could have over the control group.

10. Near the end of the Class Period, on April 16, 2019, Defendants announced that French researchers had published additional data. The publication "describe[d] outcomes in 144 COL3A1-positive vEDS patients clinically monitored and treated at the French National Referral Center for Rare Vascular Diseases (Paris, France) between the years 2000 and 2017" (the "Long-Term Observational Study"). As with the Ong Trial, that study was deeply flawed. As explained by the researchers of the study, "[i]t is difficult to formally assess this beneficial effect (the benefit of celiprolol on survival)" because the study did not have a control group.

11. Before the market opened on June 25, 2019, Acer announced that the FDA had issued a Complete Response Letter ("CRL") denying the Company's NDA for "EDSIVO." The

CRL, according to Defendants,[3] highlighted the need for Acer "to conduct an adequate and well-controlled trial," necessarily finding that the Ong Trial did not meet that threshold. Accordingly, it is clear that the FDA never agreed that no clinical development for EDSIVO was needed in addition to the Ong Trial. Given Acer's statements about its dealings with the FDA, this news shocked investors, sending the price of Acer common stock plummeting by $15.16, or over 78%, to close at $4.12 on June 25, 2019.

12. As a result of Defendants' knowing and/or reckless false and misleading statements and omissions concerning the FDA's statements to Acer about EDSIVO, the value of the price of Acer common stock during the Class Period was artificially inflated. When the FDA's issuance of the CRL revealed the truth and Acer's share price declined, Plaintiff and other Class members suffered significant losses and damages.

JURISDICTION AND VENUE

13. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder (17 C.F.R. § 240.10b-5).

14. This Court has jurisdiction over the subject matter of this action pursuant to § 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. §1331.

15. Venue is proper in this District pursuant to §27 of the Exchange Act, 15 U.S.C. §78aa and 28 U.S.C. §1391(b). Acer securities trade on the Nasdaq Stock Market ("NASDAQ") located within this District. In addition, substantial acts in furtherance of the alleged fraud or the effect of the fraud have occurred in this District. Many of the acts charged herein, including the

[3] Defendants have not made the CRL publicly available.

dissemination of materially false and/or misleading information, occurred in substantial part in this District.

16. In connection with the acts, conduct and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the United States mail, interstate telephone communications and the facilities of the national securities exchange.

PARTIES

17. Plaintiff, as set forth in the Certification submitted in connection with Plaintiff's lead plaintiff motion filed in this action, (ECF No. 14-2), acquired Acer securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosure.

18. Defendant Acer is a Delaware corporation with its principal executive offices located at One Gateway Center, Suite 351, 300 Washington Street, Newton, Massachusetts. Acer's securities trade in an efficient market on the NASDAQ under the symbol "ACER."

19. Defendant Schelling is the founder of Acer and has served as Acer's president and CEO at all relevant times.

20. Defendant Palmin has served as Acer's CFO at all relevant times. He also has served as Acer's chief operating officer ("COO") since September 1, 2018. Defendant Palmin served as president, CEO, and board director at Acer from 2013 until February 2016, as Acting CFO from February 2016 until September 2017, and as CFO until August 2018.

21. Defendants Schelling and Palmin sometimes are referred to herein as the "Individual Defendants."

22. Each of the Individual Defendants:

a. directly participated in the management of the Company;

b. was directly involved in the day-to-day operations of the Company at the highest levels;

c. was privy to confidential proprietary information concerning the Company and its business and operations;

d. was directly or indirectly involved in drafting, producing, reviewing and/or disseminating the false and misleading statements and information alleged herein;

e. was directly or indirectly involved in the oversight or implementation of the Company's internal controls;

f. certified, pursuant to the Sarbanes-Oxley Act of 2002 ("SOX"), as to the Company's compliance with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and to the Company's quarterly and annual reports filed with the Securities and Exchange Commission during the Class Period as having fairly presented, in all material respects, the financial condition and results of operations of the Company;

g. was aware of or recklessly disregarded the fact that the false and misleading statements were being issued concerning the Company; and

h. approved or ratified these statements in violation of the federal securities laws.

23. Acer and the Individual Defendants are collectively referred to herein as "Defendants."

EXPERT DR. PHILLIP LAVIN

24. Prior to filing the Amended Complaint, Plaintiff engaged Dr. Phillip Lavin who is an expert in the area of biostatistics and in the FDA drug approval process.

25. Dr. Lavin is currently the Principal of a Boston-based biostatistics consulting practice, Lavin Consulting LLC, in business for 7 years and Executive Director for a not-for-profit research foundation, Boston Biostatistics Research Foundation, in business for 31 years. In 1983, Dr. Lavin founded and served as CEO for Boston Biostatistics, Inc., which became Averion in 2001, which grew into Averion International in 2006, which, upon a merger, became Aptiv Solutions in 2011, and which was purchased by ICON plc in 2014.

26. Dr. Lavin has over 40 years of experience in the field of biostatistics as a: (1) faculty member at Brown University (2 years), Harvard School of Public Health (7 years), and Harvard Medical School (21 more years); (2) an FDA Advisory panel member and Special Government Employee (33 years); and (3) an expert consultant to the pharmaceutical, biotechnology, and medical device industries (40 years).

27. Dr. Lavin's consulting work as a Lead Biostatistician has contributed to the approval of 64 FDA-regulated products to date through NDAs (New Drug Applications), BLAs (Biologics License Applications), and PMAs (Premarket Approvals), as well as a de novo and HDE (Humanitarian Device Exemptions). Dr. Lavin has also an elected Fellow of both the American Statistical Association and the Regulatory Affairs Professional Society.

28. Dr. Lavin has participated in the design, analysis, presentation, and publication of clinical studies since 1974, after receiving his Ph.D. in Applied Mathematics from Brown University in 1972. He has authored or co-authored 191 peer-reviewed publications and have been internationally recognized for his contributions to developing biomarkers, assessing prognostic

factors for oncology studies, using cardioplegia for open heart surgery, designing more efficient Phase II cancer studies by measuring tumor dimensions instead of binary response, modeling disease response and survival, optimizing kidney transplants, and developing classifiers to diagnose disease.

29. In addition, Dr. Lavin has provided expert support as a journal reviewer for *New England Journal of Medicine*, *Journal of the American Medical Association, Journal of Clinical Oncology, Radiology*, and others.

30. Dr. Lavin reviewed the published Ong Trial data and the portions of Acer's SEC filings that are relevant to this action.

31. Dr. Lavin's expert opinion is included in relevant portions of the substantive allegations below.

SUBSTANTIVE ALLEGATIONS

Background of Acer

32. Acer was founded in December 2013 and is headquartered in Newton, Massachusetts. Acer purports to be a development-stage pharmaceutical company focused on the acquisition, development, and commercialization of therapies for serious, rare and life-threatening diseases with significant unmet medical needs.

33. On September 19, 2017, the formerly private Acer ("Private Acer") completed a reverse merger with a publicly traded corporation formerly known as Opexa Therapeutics, Inc. ("Opexa"). Companies pursue reverse mergers when they are unable to gain the backing of an underwriter and investors for a conventional initial public offering ("IPO"). In addition, the reverse merger here enabled Private Acer to "go public" quickly and access public capital while avoiding the more in-depth scrutiny of its finances and operations that comes with a traditional IPO.

34. As a result of the September 2017 reverse merger, Private Acer survived as a wholly-owned subsidiary of Opexa, and Opexa changed its name to "Acer Therapeutics Inc." and its trading symbol from "OPXA" to "ACER." The business that Opexa had formerly conducted became primarily the business conducted by Private Acer. Upon the closing of the reverse merger, the directors and the sole executive officer of Opexa resigned from their positions with Opexa, while the surviving company proceeded under the leadership of Private Acer's executive management team. On May 15, 2018, the Company changed its state of incorporation from Texas to Delaware. Following its reincorporation, the Company eliminated its holding company structure by merging the wholly-owned subsidiary Private Acer with and into the Company.

35. As of December 31, 2018, the Company had twenty-three full-time employees and no part-time employees. In addition, the Company employed a number of consultants or independent contractors.

36. Acer's product pipeline includes three clinical-stage candidates, including its most advanced product candidate, EDSIVO, as well as "ACER-001" and "osanetant." The Company has not generated any revenues from commercial sales of any of its current product candidates and has stated that its "ability to generate product revenue depends upon our ability to successfully identify, develop and commercialize these product candidates or other product candidates that we may develop, in-license or acquire in the future."

37. The Company has "not generated any revenue to date" and is "not profitable," having "incurred losses in each year since its inception in 2013." Substantially all of Acer's resources have been dedicated to the clinical development of its product candidates. Since Private Acer's inception in December 2013, the Company has spent approximately $28.5 million in research and development expenses through December 31, 2018. Of that amount, approximately

$23.6 million was directly related to EDSIVO, while only approximately $4.2 million was directly related to ACER-001, one of the Company's other clinical-stage candidates.

38. In light of the substantial investment the Company has made in each of its products candidates, particularly EDSIVO (Acer's commercial name for celiprolol), Defendants have informed investors of the importance of obtaining FDA approval for each: "Our business is substantially dependent on our ability to complete the development of, obtain marketing approval for, and successfully commercialize our product candidates in a timely manner. We cannot commercialize our product candidates in the United States without first obtaining approval from the FDA to market each product candidate." Not surprisingly, therefore, Defendants have warned investors that "our business will be substantially harmed" "if we are ultimately unable to obtain marketing approval for our product candidates."

Celiprolol is one of several similar beta-blockers prescribed off-label to treat vEDS

39. vEDS is a rare and severe inherited connective tissue disorder caused by mutations in the collagen type III alpha I chain ("COL3A1") gene that affects approximately 2,000 to 5,000 people in the United States. It causes abnormal fragility in blood vessels, which can give rise to aneurysms, abnormal connections between blood vessels known as arteriovenous fistulas, arterial dissections, and spontaneous vascular ruptures, all of which can be potentially life-threatening.

40. There are no drugs approved for the treatment of vEDS in the United States or internationally. Certain members of the beta-blocker class of drugs, which are generally used to treat high blood pressure, are prescribed off-label as part of the management of vEDS. One such beta blocker is celiprolol, which has not been approved for any indication in the United States, but has been approved for the treatment of hypertension in the European Union since 1984. Celiprolol, which is available as a low-cost generic in the European Union, is the primary drug used to treat

vEDS patients in several European countries, including France. Although celiprolol is not approved by the FDA, patients can import it for personal use, including through online pharmacies.

41. Doctors frequently prescribe beta-blockers that are similar to celiprolol off-label to treat patients with vEDS in the United States. As the Marfan Foundation[4] explained in its June 25, 2019 "Statement on Celiprolol," "Patients should be aware that there are similar third generation beta-blockers, such as carvedilol, nebivolol, and labetalol, available in the US that are being prescribed off-label for [vEDS]." The Marfan Foundation further noted that "[b]oth carvedilol and labetalol are generic; therefore, they are very low in cost, and nebivolol will soon come off patent."

42. The Ehlers-Danlos Society also confirmed in its "Consensus statement from the Ehlers-Danlos Society and professional members of the vEDS community," published on August 9, 2019, that celiprolol is just one of several similar drugs used to treat vEDS:

> There is not enough evidence to know for sure whether people with vEDS should take celiprolol or another medication to manage blood pressure to try to change the rate of arterial complications. Some medical centers with expertise in vEDS use celiprolol for their patients. Other medical centers with expertise in vEDS use other blood pressure medications. Since there is not one clear best option right now, people with vEDS should talk with their health care provider to create a plan based on their personal medical history.

In preparation for its push to commercialize celiprolol in the United States under the name EDSIVO, Acer Acquired the rights to an old study of the drug instead of conducting new research.

43. In January 2015, the FDA approved Orphan Drug Exclusivity for EDSIVO. Orphan Drug Exclusivity provides seven years of marketing exclusivity upon the approval of a drug

[4] Marfan's Syndrome is in the same family of diseases as vEDS. The Marfan Foundation advances research for treatments that save lives and enhance quality of life for affected people. Its goal is to provide the latest and most accurate information, to educate patients, families, medical professionals and the general public about Marfan syndrome and related disorders.

intended to treat a rare condition. During that time the FDA will not approve any other drug for the same indication unless it demonstrates clinical superiority.

44. The purpose of Orphan Drug Exclusivity is to promote the development of drugs to treat rare diseases. Acer, however, did not intend to conduct an additional clinical study of EDSIVO. Instead, as stated in a December 13, 2016 press release, Acer signed an agreement with Assistance Publique—Hôpitaux de Paris, Hôpital Européen Georges Pompidou ("AP-HP") in Paris, France granting Private Acer exclusive rights to access and use data from a previously published study of celiprolol.

45. In 2004, researchers at AP-HP published data on vEDS patients, observing that an abnormally low intima-media thickness generates a higher wall stress than in control subjects at the site of an elastic artery, which may increase the risk of arterial dissection and rupture. Based on this observation, the investigators aimed to assess the preventive effect of celiprolol for major cardiovascular events in patients with vEDS via a multicenter, prospective, randomized, open trial with blinded evaluation of clinical events in the Ong Trial. Results from the Ong Trial were published on October 30, 2010 in *The Lancet*, a weekly, peer-reviewed medical journal. The Ong Trial was funded by the French Ministry of Health, and the principal investigator for the study was Professor Pierre Boutouyrie.

46. As described in a September 25, 2017 press release, Acer conducted a "retrospective source verified analysis" of the data from the Ong Trial instead of a new study.

47. Even though celiprolol is a cheap generic drug in the European Union and Acer did not conduct any new studies of the drug, analysts following Acer expected that if EDSIVO was approved, Acer would be able to charge each patient more than $100,000 a year for the drug, in line with prices for other drugs with orphan status.

Acer raised money from investors by claiming that the FDA "agreed" that "additional clinical development" beyond the Ong Trial was "not needed."

48. Shortly after the completion of its reverse merger in September 2017, Acer used its new status as a public company to raise money from investors in a secondary public offering of stock.

49. In a Preliminary Prospectus Supplement filed with the SEC on December 11, 2017, and Prospectus Supplement filed with the SEC on December 12, 2017, Defendants reported that Acer and the FDA had reached an agreement that Acer would not need to conduct any clinical development beyond the already-completed Ong Trial. Defendants stated that at a September 2015 meeting at which Acer "met with the FDA to discuss the existing clinical data for EDSIVO," "***the FDA agreed that additional clinical development is not needed*** and stated that we may submit a 505(b)(2) NDA for EDSIVO™ for the treatment of vEDS" (emphasis added).

50. On March 7, 2018, the Company filed with the SEC its annual report on Form 10-K for the fiscal year ended December 31, 2017 ("2017 10-K"). In the 2017 10-K, Defendants continued to assure investors that the FDA would approve EDSIVO based on the Ong Trial: "In September 2015, we met with the FDA to discuss the existing clinical data for EDSIVO. ***At that meeting, the FDA agreed that an additional clinical trial is not likely needed*** and stated that we may submit a 505(b)(2) NDA for EDSIVO™ for the treatment of vEDS" (emphasis added).

51. Notably, the 2017 10-K differed from the Preliminary Prospectus in that Acer slightly revised its description of the FDA meeting. Instead of unambiguously stating that "additional clinical development" was "not needed," Acer limited the statement in the 2017 10-K to an "an additional clinical ***trial***" instead of the more general term "***development***" and stated that it was "not ***likely*** needed."

52. In a Preliminary Prospectus Supplement filed with the SEC on July 31, 2018, and in a Prospectus Supplement filed with the SEC on August 1, 2018 for another secondary offering, Defendants repeated their revised description of the September 2015 meeting.

53. Several things are clear from Defendants revision of their description of Acer's agreement with the FDA at the September 2015 meeting. *First*, given that Acer altered the statement without explanation and without alerting investors to the change, the statement was clearly intended to continue to assure investors that the FDA had agreed to approve EDSIVO based on the Ong Trial and to generally affirm Acer's earlier, more definitive statement. *Second*, the first statement, in which Acer unambiguously stated that the FDA "agreed that additional clinical development is not needed" was false. If the statement had been true, there would have been no need to revise it to add "likely" and to change "development" to "trial." *Third*, the fact that Defendants revised the initial statement about the meeting shows that they knew it was false. They, however, did not advise investors of their misstatement. Instead, ***after their successful stock offering***, Defendants subtly revised the statement so that it was still false and misleading, but they would have a little more leeway if investors ever found out that Acer did not actually have an agreement with the FDA (which they did when the FDA rejected EDSIVO's NDA).

Acer's statements concerning its agreement with the FDA were highly material to investors because the Ong Trial was Deeply Flawed.

54. The Ong Trial only enrolled 53 participants, who were randomized at eight centers in France and one center in Belgium. The primary endpoint was a composite of cardiac or arterial events (rupture or dissection, fatal or not) during follow-up. Secondary endpoints were gastrointestinal or uterine rupture. According to Acer's filings with the SEC, the study was ended early "after a consensus decision of the safety monitoring board, the methodologist of AP-HP, and the principal investigator because significant differences were recorded between the treatment

group and the control group after 64 months." "[W]ith celiprolol the risk of having a cardiac or arterial event," according to Defendants, "was reduced by 64% compared to [the] control [group]." Acer also boasted in a September 25, 2017 press release concerning the completion of its source verified analysis of the Ong Trial data that the Ong Trial had been a "robust clinical study" and had "achieved statistical significance."

55. The Ong Trial, however, suffered obvious fatal flaws and those flaws were clear from both the published results in the *Lancet* and in Acer's public filings with the SEC. In addition to the small size of its participant pool, during the course of the Ong Trial, researchers learned that more than one-third of the participants did not have a COL3A1 gene mutation, which is the cause of vEDS. Further, the absence of such a genetic mutation was not evenly distributed between the celiprolol arm of the study and the control group. While 12 of the 25 patients in the celiprolol arm did not have a proven COL3A1 mutation, only 8 out of the 28 patients in the control group did not have the proven genetic mutation.

56. Plaintiff asked Expert Lavin to opine about why the FDA determined that that the Ong Trial was not an adequate and well controlled study sufficient for the approval for EDVISO. Expert Lavin identified several red flags about the study that the FDA would have immediately recognized and made it unlikely that the FDA would find that the study was adequate and well controlled. The red flags he identified were: (1) the genetic mutation imbalance provided a clear-cut bias in favor of the group of patients taking celiprolol versus the control group; (2) insufficient sample size made it underpowered and therefore unable to test a clinically realistic advantage that celiprolol could have over the standard of care; (3) inclusion of such a high percentage of people in the study who did not have the mutation that causes vEDS (ineligible patients) was not good

clinical practice; and (4) the study was retrospective, which introduced selection bias.[5]

57. The Genetic Mutation Imbalance. Expert Lavin explained that the Ong Trial bias can be quantified from the percentages of the study's participants who did not have the genetic mutation, which was 48% (12 out of 25) for the treatment group and 28.6% (8 out of 28) for the control group. From the outset, the treatment group had a 19.4% head start towards event-free survival, which is highly material and equates to a 5-event advantage for the treatment group. Given that an 8-event advantage reaches statistical significance, any scenario among the 13 treatment cases and the 20 control cases with the mutation where there are just 3 fewer events in the mutation-present treatment group will result in a statistically significant event-free survival advantage. Accordingly, this means that the treatment group had a 5-event head start over the control group towards reaching statistical significance (8-event advantage). This is a red flag that the FDA would immediately have recognized as a bias upon reviewing the mutation data.

58. Expert Lavin further explained with respect to the remaining 33 cases (13+20) with mutations, there was less than 80% power to detect a 50% difference (*i.e.,* 25% vs. 75%), rendering the Ong Trial subgroup very underpowered (too small). In other words, after excluding the ineligible cases, the study lacked an adequate sample size to test for a meaningful difference between the two groups and, therefore, was unlikely to yield any conclusive results. This is another red flag that the FDA would have recognized as soon as the agency learned about the 20 (12+8) ineligible cases.

59. Expert Lavin opined that the observation of an imbalance between the treatment group and the control group would generally lead the FDA to conclude that a study was not "well-controlled" and that the severe imbalance observed here, between the experimental and control

[5] Selection bias is defined as the intentional choice of a favorable result when there are multiple possible choices.

arms of the Ong Trial with respect to the number of patients with the COL3A1 mutation, prevented the FDA from concluding that the Ong Trial was an "adequate and well-controlled" study.[6]

60. Insufficient sample size made it underpowered. Another source of bias in the Ong Trial that Expert Lavin identified is that the study was underpowered because it was only able to enroll 53 of the targeted 100 participants (Scenario A) and only 33 (Scenario B) of them had the mutation that caused vEDS. The following table demonstrates the 5-year survival advantages that would be needed with a total of 53 and 33 subjects to be randomized 1:1 between celiprolol versus standard of care ("SOC") to achieve 80% power according to a two-sided log rank test with 5% error rate. Scenario A can only test a 50% versus 88% 5-year survival while Scenario B can only test a 50% versus 98% 5-years survival, which are both unrealistically optimistic. Expert Lavin found that this represented a major deficiency because FDA could easily run these calculations to conclude that the study was underpowered and therefore unable to test a clinically realistic advantage that celiprolol could have over the current standard of care (most likely lower than 88%).

[6] *See* 21 C.F.R. § 314.126(b), which provides that an "adequate and well-controlled study" is characterized by, among other things, the use of "a design that permits a valid comparison with a control to provide a quantitative assessment of drug effect," "the method of selection of subjects provides adequate assurance that they have the disease or condition being studied, or evidence of susceptibility and exposure to the condition against which prophylaxis is directed," "the method of assigning patients to treatment and control groups minimizes bias and is intended to assure comparability of the groups with respect to pertinent variables," and "adequate measures are taken to minimize bias on the part of the subjects, observers, and analysts of the data."

	Scenario	
	A	**B**
Test significance level, α	0.050	0.050
1 or 2 sided test?	2	2
SOC % alive at 5 years, π_1	50%	50%
Celeprolol % alive at 5 year, π_2	88%	98%
Hazard ratio, $h=\ln(\pi_1) / \ln(\pi_2)$	5.422	34.310
Power (%)	80	80
Total number of subjects	53	33
Total number of arterial events required, D	11	3

61. Inclusion of such a high percentage of ineligible patients was not good clinical practice. Another concern raised by Expert Lavin based on the Ong Study's high percentage (37.7%, 20/53) of ineligible subjects is that the FDA would expect that the study to be conducted under 21 CRF Part 312 or The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use standards. In Dr. Lavin's experience, any ineligibility rate in excess of 10% would not have met these standards and would concern the FDA.

62. The Ong Trial was a retrospective study. Finally, another significant source of bias in the Ong Trial that Expert Lavin identified is that the FDA would consider it a retrospective study because Acer knew the results of the Ong Trial before it decided to file with the FDA. The FDA has a strong preference for prospective studies because use of retrospective studies allows a drug's sponsor to shop around for a study with a positive result and ignore studies with negative results. Based on this, any claims of statistical significance would not be "controlled." Accordingly, the FDA has longstanding policies that retrospective studies are not sufficient for approval under certain or most circumstances. In Expert Lavin's opinion, FDA would have recognized this bias as soon as it learned that that the Ong Trial was a purchased retrospective study.

63. Several additional sources agree with Expert Lavin's assessment that the Ong Trial had numerous red flags that made FDA approval unlikely.

64. On January 28, 2019, *Pharmaceutical Technology* published an article on its website entitled "Why the experts say Acer is unlikely to get FDA nod for vEDS drug." In line with the opinion of Expert Lavin, the article stated that "Acer Therapeutics' Edsivo (celiprolol) is not expected to win approval from the US Food and Drug Administration (FDA) for vascular Ehlers-Danlos syndrome (vEDS), as the registrational trial was too small and not well-controlled, according to experts." Experts interviewed said "that given the trial comprised of 53 patients, the Phase IV trial (NCT00190411) was too small even for a rare disease like vEDS." Expert in vEDS, Dr Harry Dietz, Co-director of the Medical Genetics Fellowship Training Programme and Professor of Pediatrics at The Johns Hopkins Hospital said that "[the] study that the approval of Edsivo would be based on was not well-designed, with an overall small trial size." The article further stated that Dr. Dietz and Dr. Paul Grossfeld, Pediatric Cardiologist with the Rady Children's Hospital, San Diego, California, said that "[b]esides the low patient figures, the imbalance between the experimental and control arms in terms of patients with the COL3A1 mutation means the results are also insufficient for FDA approval." The authors of the article contacted Acer, but Acer declined to comment.

65. The Ehlers-Danlos Society and Marfan Foundation's statements on celiprolol also support the position that the Ong Trial was flawed. Both statements indicated that the organizations' longstanding view was that the Ong Trial was not sufficient to show that celiprolol is effective against vEDS.

66. The Ehlers-Danlos Society's "Consensus statement from the Ehlers-Danlos Society and professional members of the vEDS community," published on August 9, 2019, stated that

"[t]here is not enough evidence to know for sure whether people with vEDS should take celiprolol or another medication to manage blood pressure to try to change the rate of arterial complications."

67. The Marfan Fountain's June 25, 2019 "Statement on Celiprolol" discussed the limitations of the Ong Trial and said stated that "[t]he Marfan Foundation, as well as representatives of its Professional Advisory Board, have reviewed the underlying studies of the drug and agree that celiprolol does not warrant designation as a sole approved drug for the treatment of people with vEDS." The statement further said that the "consensus expressed at the international vascular Ehlers-Danlos syndrome meeting in Amsterdam in May 2018 emphasized the need for a large and well-controlled clinical trial of celiprolol in vEDS and the eagerness of the international medical community to assist in this effort."

68. Plaintiff's investigator spoke with a senior officer at the Marfan Foundation (the "Marfan Senior Officer") who had held her position since 2016 and help draft the "Marfan Foundation Statement on Celiprolol." The Marfan Senior officer said that the statement was approved unanimously by all 18 members of the foundation's Professional Advisory Board and was driven by cardiologist and geneticists. The Marfan Senior Officer further stated that the Professional Advisory Board did not want to see the drug move forward in the United States because they believed the Ong Trial "was way too small and the results were not significant enough" to support approval. The Marfan Senior Officer also stated that that the Professional Advisory Board did not want to support approval for a very expensive drug when its efficacy was "not even marginal." The Marfan Foundation issued the statement to show vEDS patients that experts on the disease had found the FDA's decision to be sound.

69. The Marfan Senior Officer attended a symposium on vEDS held by the DEFY Foundation that was attended by international physicians and researchers who are experts on

vEDS. The DEFY symposium was held the day before the Marfan Foundation hosted an international research symposium in Amsterdam, Netherlands in May 2018. One of the attendees of the DEFY symposium was an American white male who identified himself as an Acer employee. The Senior Marfan Official believed he was an executive at Acer with a scientific background. According to the Senior Marfan Officer, some attendees at the meeting questioned the size and results of the clinical trial that Acer was using to seek FDA approval.

70. The Marfan Senior Official also told Plaintiff's investigator about having heard that Acer employees had met with the Marfan Foundation's Professional Advisory Board about EDSIVO and several members of the board told the Acer employees that they did not support approval for the drug.

71. Given the substantial flaws in the Ong Trial and the public information about it, there is no doubt that Acer's statement that "the FDA agreed that additional clinical development is not needed" and similar statements were highly material to investors' view of the prospects of EDSIVO's NDA and the value of Acer's stock and that Acer would have known that.

The FDA's Process for Reviewing Acer's NDA for EDSIVO

72. Every drug that has reached the U.S. market since 1938 has been the subject of an NDA, the vehicle through which drug sponsors formally propose that the FDA approve a new pharmaceutical for sale and marketing in the U.S. According to the FDA website,[7] "[t]he goals of the NDA are to provide enough information to permit FDA reviewer to reach the following key decisions:

a. whether the drug is safe and effective in its proposed use(s), and whether the benefits of the drug outweigh the risks;

[7] *See* https://www.fda.gov/drugs/types-applications/new-drug-application-nda.

b. whether the drug's proposed labeling (package insert) is appropriate, and what it should contain; and

c. whether the methods used in manufacturing the drug and the controls used to maintain the drug's quality are adequate to preserve the drug's identity, strength, quality, and purity.

73. "The documentation required in an NDA," according to the FDA website,[8] "is supposed to tell the drug's whole story, including what happened during the clinical tests, what the ingredients of the drug are, the results of the animal studies, how the drug behaves in the body, and how it is manufactured, processed and packaged."

74. According to Acer's Form 10-K for the fiscal year ended December 31, 2018 that it filed with the SEC on March 7, 2019 ("2018 10-K"):

> The FDA is required to conduct a preliminary review of an NDA within the first 60 days after submission, before accepting it for filing, to determine whether it is sufficiently complete to permit substantive review. The FDA may accept the NDA for filing, potentially refuse to file the NDA due to deficiencies but work with the applicant to rectify the deficiencies (in which case the NDA is filed upon resolution of the deficiencies) or refuse to file the NDA. The FDA must notify the applicant of a refusal to file a decision within 60 days after the original receipt date of the application. … Once an NDA is accepted for filing, the FDA begins an in-depth substantive review. Under the Prescription Drug User Fee Act ("PDUFA") and the FDA's commitments under the current PDUFA Reauthorization Act, the FDA has a goal of reviewing and acting on 90% of standard non-priority NDA applications within ten months from the filing date of the NDA.

75. As Acer's statement indicates, an "in-depth substantive review" of an NDA does not take place until after an NDA is accepted for filing.

76. Expert Lavin, based on his extensive experience working for the FDA (33 years)

[8] *See id.*

and on NDAs (40 years), opined that the FDA acceptance of an NDA for filing is a weak indicator of its substantive merit and likelihood of success. According to him, to determine if it should accept an NDA for filing, the FDA only reviews an NDA for its completeness rather than for substantive content.

77. The PDUFA also provides for a "priority review" designation, which enables applicants that have submitted NDAs meeting certain criteria to receive a decision within 6 months, instead of the 10-month period under standard review. According to the FDA's website:[9]

> A Priority Review designation will direct overall attention and resources to the evaluation of applications for drugs that, if approved, would be significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to standard applications.
>
> Significant improvement may be demonstrated by the following examples:
>
> - evidence of increased effectiveness in treatment, prevention, or diagnosis of condition;
> - elimination or substantial reduction of a treatment-limiting drug reaction;
> - documented enhancement of patient compliance that is expected to lead to an improvement in serious outcomes; or
> - evidence of safety and effectiveness in a new subpopulation.
>
> FDA decides on the review designation for every application. However, an applicant may expressly request priority review as described in the Guidance for Industry Expedited Programs for Serious Conditions – Drugs and Biologics. It does not affect the length of the clinical trial period. FDA informs the applicant of a Priority Review designation within 60 days of the receipt of the original BLA, NDA, or efficacy supplement. Designation of a drug as "Priority" does not alter the scientific/medical standard for approval or the quality of evidence necessary.

[9] *See* https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/priority-review.

78. In Expert Lavin's opinion, based on this extensive experience working for the FDA and on NDAs, is that the FDA generally grants priority review status based on theoretical considerations about whether a drug would provide a significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to standard applications, not based on the actual quality of the clinical trial data in an NDA. Accordingly, it is Expert Lavin's opinion that a grant of priority review status is not a strong indicator of the quality of the clinical trial data in an NDA.

79. After conducting its review centered on the drug candidate's safety and efficacy, the FDA then issues its decision by letter either approving the NDA or else rejecting or denying the NDA. If the FDA rejects or denies the NDA, it issues a CRL, which must, under 21 C.F.R. § 314.110(a)(1), contain "all of the specific deficiencies that the agency has identified":[10]

> The FDA reviews an NDA to determine, among other things, whether the drug is safe and effective for its intended use and whether the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, quality and purity. The FDA is required to refer an application for a novel drug to an advisory committee or explain why such referral was not made. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation in response to specific questions raised by the FDA, which may include whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.
>
> * * *
>
> After the FDA evaluates the NDA and conducts its inspections, it may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug subject

[10] Note, however, that "[i]f FDA determines, after an application is filed or an abbreviated application is received, that the data submitted are inadequate to support approval, the agency might issue a complete response letter without first conducting required inspections and/or reviewing proposed product labeling." *Id.* § 314.110(a)(3).

> to specific prescribing information for specific indications and, if applicable, specific post-approval requirements. A Complete Response Letter indicates that the review cycle of the application is complete and the application is not ready for approval. After receiving a Complete Response Letter, the applicant must decide within twelve months (subject to extension), if it wants to resubmit the NDA addressing the deficiencies identified by the FDA in the Complete Response Letter, withdraw the NDA, or request an opportunity for a hearing to challenge the FDA's determination. A Complete Response Letter may require additional clinical data and/or an additional pivotal Phase 3 clinical trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, nonclinical studies or manufacturing. Even if such data are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret data.

As part of its standard procedures, the FDA would have made Acer aware of its concerns about the Ong Trial prior to when Acer filed its NDA for EDSIVO

80. In Expert Lavin's opinion, it is standard practice for sponsors of a drug, such as Acer, to have numerous meetings with FDA officials prior to filing an NDA.

81. According to Expert Lavin, sponsors are represented at meetings with the FDA by at least 5 members of the sponsor's senior management. Generally, the sponsor's chief medical officer, director of clinical affairs, and director of regulatory affairs attend such meetings. On some occasions, these senior officers will be accompanied by the sponsor's chief executive officer. Sponsors send written questions to the FDA and it is the FDA's policy to respond to the questions in writing prior to the meeting.

82. Expert Lavin further opined that Sponsors always maintain written notes and records from such meetings so that they are clear on the FDA's feedback and their path forward. All agreements reached between the FDA and a sponsor during a meeting are recorded, and the minutes of meetings between a sponsor and the FDA are prepared by the FDA and sent to the

sponsor. Generally, the sponsor knows well the outcome of a meeting, with the FDA's minutes reflecting the points discussed at the meeting.

83. According the Expert Lavin, Acer's SEC filings show the numerous meetings and extensive communication between Acer and the FDA that he would have expected based on his experience with the FDA and NDAs.

84. On March 7, 2018, the Company filed the 2017 10-K. In the 2017 10-K, Defendants stated that "[i]n September 2015, we met with the FDA to discuss the existing clinical data for EDSIVO."

85. Also in the 2017 10-K, Defendants reported that "[i]n May 2017, we held a Type C[11] meeting with the FDA to discuss non-clinical and manufacturing data, and proactively identify whether there were any gaps for us to address in advance of a pre-NDA meeting." In addition, Defendants stated that "the FDA provided us with additional guidance on the expected presentation of the existing clinical data for EDSIVO to support the NDA filing." Further, Defendants advised the market that they "plan[ned] to have a pre-NDA meeting, which may consist of one or more consults, with the FDA in the second quarter of 2018," after which they expected "to submit the 505(b)(2) NDA for EDSIVO for the treatment of vEDS at the end of the first half of 2018."

86. Moreover, in a press release issued on March 7, 2018 ("March 7, 2018 Press Release"), Defendants told investors of their "plan to discuss these key data," consisting of the "positive results" obtained from the Company's own "retrospective source-verified analysis of the trial data, including the primary and secondary endpoints, confirm[ing] the data from a previously published randomized controlled clinical study of celiprolol," "during a pre-NDA meeting with the FDA in the second quarter of 2018."

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[11] An explanation of the types of meetings that the FDA holds with sponsors can be found here: https://www.fda.gov/drugs/data-standards-manual-monographs/industry-meeting-type.

87. On August 13, 2018, Defendants issued a press release (the "August 13, 2018 Press Release") announcing the Company's financial results for the second quarter of the 2018 fiscal year. In the August 13, 2018 Press Release, Defendants reported that they had "held a Type C clinical meeting and a Type B (pre-NDA) meeting with the FDA in June 2018" and were "targeting NDA submission to the FDA for EDSIVO for the treatment of vEDS in early fourth quarter of 2018."

88. According Expert Lavin, based on his review of the Ong Trial and his knowledge of standard FDA practices, top officials from Acer would have attended the meetings described in the Company's filings and it is near certain that FDA officials would have discussed the following concerns about the Ong Trial (*see* Paragraphs 56-62): (1) The genetic mutation imbalance provided a clear-cut bias in favor of the group of patients taking celiprolol versus the control group; (2) insufficient sample size made it underpowered and therefore unable to test a clinically realistic advantage that celiprolol could have over the standard of care; (3) inclusion of such a high percentage of people in the study who did not have the mutation that causes vEDS (ineligible patients) was not good clinical practice; and (4) the study was retrospective, which introduced selection bias.

89. In Expert Lavin's opinion, these problems with the Ong Trial would be known to the FDA, so the FDA would not have "agreed" that additional clinical development was not needed for EDSIVO and the FDA's lack of agreement would have been clear to Acer long before Acer submitted its NDA for EDSIVO.

90. Expert Lavin further opined that the FDA proactively gives feedback about the clinical trials and data before a company submits an NDA and the general practice is that the FDA's concerns are worked out prior to the submission of the application. Accordingly,

statements by the FDA prior to filing an NDA would have focused on whether the NDA would be approved, not on whether the sponsor of a drug could submit the NDA.

91. In the August 13, 2018 Press Release, Defendants also stated that they had "presented celiprolol vEDS Patient Registry data to the FDA at the Type C meeting." The manuscript of the patient registry data, according to Defendants, was then "currently under peer review" and, "if published, it will be included in support of NDA but is not rate-limiting to submission of NDA."

92. Accordingly, Defendants' public statements indicate that Acer had discussed all the portions of EDSIVO's NDA (the Ong Trial data, Acer's own "retrospective source-verified analysis" of the Ong Trial data, and the Long-term Observational Study) with the FDA prior to the Company's submission of the NDA.

93. Even in the face of FDA criticism of its EDVISO's NDA, Defendants would have been highly motivated to avoid conducting a new prospective trial for EDSIVO because conducting such a trial would be incredibly expensive and time consuming. In Expert Lavin's opinion, the FDA would prefer a randomized clinical trial with a 1:1 allocation between celiprolol plus standard of care versus the standard of care alone. To detect a 20% absolute advantage in 5-year all-cause survival from 50% to 70% with 80% power for a two-sided log rank test with 5% error, 96 vEDS subjects would be required per treatment group with 71 arterial events[12] required to complete the study. Assuming two years to recruit a total of 200 EDS subjects, it would take 7 to 8 years to reach the targeted number of arterial events (71). Given that it would be a difficult international study to coordinate, the estimated cost of the trial would be $40,000 per subject or $8,000,000 total (for 200 patients) when the cost of study drugs, study-directed testing, patient

[12] Arterial events were the primary endpoint of the Ong Trial.

follow-up visits, a contract research organization, and site costs are considered. The cost estimate would include a Data Safety Monitoring Committee, a Steering Committee, and a Clinical Endpoint Committee to evaluate disease-specific progression as a surrogate for mortality.

In the year leading up to Acer's submission of its NDA for EDSIVO and while the NDA was under submission, it continued to signal to the market that the FDA had agreed to approve it.

94. In the year leading up to Acer's submission of its NDA for EDSIVO and after it submitted the NDA, Defendants continued to send signals to the market that FDA approval was virtually certain.

95. On February 5, 2018, Acer issued a press release ("February 5, 2018 Press Release") announcing the expansion of its management team. Defendants stated that they had hired three new executives and "one new key hire." The February 5, 2018 Press Release reported that the Company had "appointed Terrie Kellmeyer, Ph.D., as Vice President, Clinical Science; John Klopp as Vice President, Manufacturing; and Jason Kneeland, CPA, as Vice President Finance, Controller. Also, the Company hired Kim Tharaldsen, MBA, as Senior Director, Marketing."

96. In the March 7, 2018 Press Release, Defendants stated that they planned to make "additional senior-level commercial and medical affairs hires this year, as well as continuing to build out the commercial team and add other core personnel later this year."

97. On May 14, 2018, Defendants issued a press release ("May 14, 2018 Press Release") announcing that it had "appointed Don Joseph, as Chief Legal Officer; Stacey Bain, Ph.D., as Vice President, Clinical Operations; Kristin Mulready, as Vice President, Program and Alliance Management; and Matt Seibt, as Vice President, Market Access and Reimbursement." The May 14, 2018 Press Release also noted the February 2018 appointments of Terrie Kellmeyer, Ph.D., as Vice President, Clinical Science; John Klopp as Vice President, Manufacturing; and Jason Kneeland, CPA, as Vice President Finance, Controller. All told, Defendants had "expanded

[the Company's] management team by hiring a Chief Legal Officer and six Vice Presidents." These "additional senior-level hires," according to the May 14, 2018 Press Release, "bring deep industry knowledge and experience with them, which will be invaluable as we move forward." Defendants also reported that they were "continuing pre-commercial activities for EDSIVO" and would be "making additional senior-level commercial and medical affairs hires this year, as well as continuing to build out the commercial team and add other core personnel later this year."

98. In the August 13, 2018 Press Release, Defendants announced that it had made "two important senior-level hires," Dr. Usman Iqbal as Vice President, Medical Affairs and Ms. Nancy Duarte-Lonnroth as Vice President, Quality, "[a]s part of the pre-commercial preparation." Like the new hires announced in May 2018, Iqbal and Duarte-Lonnroth "bring deep industry knowledge and experience across medical affairs and quality, which will be invaluable as we move forward," according to Defendants. The August 13, 2018 Press Release also noted that Acer planned on "making additional senior-level commercial hires this year, as well as continuing to build out the commercial team and add other core personnel later this year."

99. On October 29, 2018, Defendants issued a press release ("October 29, 2018 Press Release") announcing that Acer had submitted its NDA for EDSIVO. Defendants also reported in the October 29, 2018 Press Release that the Company had "requested Priority Review, which if granted, could result in a six-month review period," while noting that "Priority Review is a designation given to drugs that offer a significant improvement in treatment or provide treatment where no satisfactory alternative therapy exists." The October 29, 2018 Press Release quoted Dr. William Andrews, Acer's chief medical officer, as stating: "We now look forward to continuing to work with the FDA as they review our NDA, with hopes to make EDSIVO available as quickly as possible in the U.S."

100. On December 26, 2018, Defendants issued a press release ("December 26, 2018 Press Release") announcing that the FDA had accepted for review the Company's NDA for EDSIVO. The December 26, 2018 Press Release also noted that "[t]he FDA also granted a priority review of the NDA and assigned a Prescription Drug User Fee Act (PDUFA) target action date of June 25, 2019. Priority review is a designation granted by the FDA to accelerate the review process for drugs that offer a significant improvement in treatment or provide treatment where no satisfactory alternative therapy exists." In addition, in the December 26, 2018 Press Release Defendants stated that "[w]e continue to accelerate our pre-commercial activities supporting the potential U.S. launch of EDSIVO for the treatment of vEDS if it is approved by the FDA."

101. On April 16, 2019, Defendants issued a press release ("April 16, 2019 Press Release") announcing the publication of the Long-Term Observational Study, "long-term data from a cohort of COL3A1-positive vEDS patients in the *Journal of the American College of Cardiology*" based on a registry of vEDS patients in France. According to the April 16, 2019 Press Release, the Long-Term Observational Study, entitled "Vascular Ehlers-Danlos Syndrome: Long-Term Observational Study," and authored by Michael Frank, MD, Xavier Jeunemaitre, MD, PhD, and Pierre Boutouyrie, MD, PhD, et al., "describes outcomes in 144 COL3A1-positive vEDS patients clinically monitored and treated at the French National Referral Center for Rare Vascular Diseases (Paris, France) between the years 2000 and 2017." The April 16, 2019 Press Release quotes Dr. Michael Frank, a clinical investigator from the Paris Group and one of the co-authors of the Long-Term Observational Study, as stating, "The higher overall survival in patients treated with celiprolol in this long-term study in COL3A1-positive vEDS patients appears to correlate with the significant event-free survival advantage that was reported in the [Ong Trial] of celiprolol treatment in vEDS patients." The April 16, 2019 Press Release also quoted Acer's chief medical

officer as stating: "We are pleased to see this publication from the vEDS clinical investigator group in Paris which provides patients and physicians with a greater understanding of this chronic disease, including data suggesting a positive impact of celiprolol, which has a unique pharmacological profile."

102. In a May 14, 2019 Press Release, Acer stated: "[I]n April 2019, we announced the publication of the Paris registry data in JACC that supplements the previously-reported safety and efficacy of celiprolol in vEDS patients with a confirmed type III collagen (COL3A1) mutation."

103. While touting the supposedly "positive impact of celiprolol" supposedly observed in the Long-Term Observational Study, the April 16, 2019 and May 14, 2019 Press Releases failed to mention the significant limitations of that study. According to the researchers of the Long-Term Observational Study themselves, "[i]t is difficult to formally assess this beneficial effect (the benefit of celiprolol on survival) in the absence of a placebo-controlled prospective trial, because other confounders might have influenced this observation." As Dr. Julie De Backer and Dr. Tine De Backer, vEDS researchers not affiliated with the Long-Term Observational Study, stated:

> Whether the systematic treatment with celiprolol has an additional genuine pharmacological beneficial effect or helps ensure better follow up cannot be answered with this study. The only way to determine if it is celiprolol contributing to the better outcome is to conduct a randomized prospective trial comparing celiprolol to another beta-blocker in patients with molecularly confirmed vEDS.[13]

The FDA Issues a CRL to Acer for EDSIVO, revealing that it had never agreed that additional clinical development was not needed for EDSIVO.

104. On June 25, 2019, Defendants issued a press release ("June 25, 2019 Press Release") disclosing that the FDA had rejected Acer's NDA for EDSIVO. Although Defendants

[13] De Backer, Julie and Tine De Backer, "Vascular Ehlers-Danlos Syndrome Management: The Paris Way, A Step Forward on a Long Road," *Journal of the American College of Cardiology*, Vol. 73, Issue 15 (April 2019).

did not make the CRL available to the public, the June 25, 2019 Press Release reported that the CRL had cited the need for an "adequate and well-controlled trial" evaluating EDSIVO's effectiveness in reducing the risk of clinical events in patients with vEDS. The June 25, 2019 Press Release also quoted Defendant Schelling as stating the following: "We remain committed to working closely with the FDA to fully understand its response. We expect to respond to the FDA in the third quarter of this year."

105. On July 5, 2019, Defendants issued a press release ("July 5, 2019 Press Release") announcing that, in light of the FDA's issuance of the CRL to Acer regarding its NDA for EDSIVO, the Company was undergoing a "corporate restructuring," as a result of which "Acer's headcount has been reduced from 48 to 19 employees and pre-commercial activities of EDSIVO (celiprolol) have been halted. The restructuring is expected to provide the resources needed for Acer to conduct its planned business operations through 2020." The July 5, 2019 Press Release also noted that Defendants "intend to continue our dialogue with the FDA to fully understand its response and work toward our goal of approval of EDSIVO." Defendants added that "[i]n light of the CRL it was necessary to reduce our expenses, extend our cash runway, and focus our resources on a potential path forward for EDSIVO as well as continued development of our other pipeline opportunities."

MATERIALLY FALSE AND MISLEADING STATEMENTS ISSUED DURING THE CLASS PERIOD

106. After the market closed on December 11, 2017, Acer announced a secondary public offering of common stock[14] and filed its Preliminary Prospectus Supplement with the SEC.

[14] Research shows that the share price of a company generally drops when it announces a secondary offering.

("December 11, 2017 Preliminary Prospectus Supplement").[15] In the December 11, 2017 Preliminary Prospectus Supplement, Defendants stated:

> ***In September 2015, we met with the FDA to discuss the existing clinical data for EDSIVO. At that meeting, the FDA agreed that additional clinical development is not needed and stated that we may submit a 505(b)(2) NDA for EDSIVO for the treatment of vEDS.*** In addition, the FDA advised us that no significant additional work would be required for the chemistry, manufacturing and controls, nonclinical or pharmacology sections of the NDA. The FDA also indicated to us at that time that it expected that the 505(b)(2) NDA for EDSIVO would qualify for priority review, which provides an expedited six-month review cycle, instead of the traditional ten-month cycle, for a drug that treats a serious condition and demonstrates the potential to be a significant improvement in safety or effectiveness of the treatment, prevention, or diagnosis of the condition. The FDA determines whether an application will receive priority review at the time the application is submitted. We expect to submit to the FDA the 505(b)(2) NDA for EDSIVO for the treatment of vEDS in the first half of 2018. (Emphasis added).

107. The foregoing statements were materially false and misleading because Defendants knew or recklessly disregarded that the FDA did not enter into any such agreement with Defendants that no further clinical development would be required for Acer to obtain FDA approval for EDSIVO. By misrepresenting the FDA's communications to Acer regarding the need for further clinical development to obtain FDA approval, Defendants misled investors about the likelihood of and timeline for FDA approval of EDSIVO.

108. On March 7, 2018, Acer filed the 2017 10-K with the SEC. Defendants Schelling and Palmin signed the 2017 10-K and the 2017 10-K also contained certifications required pursuant to SOX that Schelling and Palmin signed. The 2017 10-K stated:

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[15] On December 12, 2017, Acer filed with the SEC its Prospectus Supplement, which is at least substantially similar, if not virtually identical, to the December 11, 2017 Preliminary Prospectus Supplement. The December 11, 2017 Preliminary Prospectus Supplement and December 12, 2017 Prospectus Supplement formed part of a registration statement signed by Defendants Schelling and Palmin. The language quoted immediately below is identical.

> ***In September 2015, we met with the FDA to discuss the existing clinical data for EDSIVO. At that meeting, the FDA agreed that an additional clinical trial is not likely needed*** and stated that we may submit a 505(b)(2) NDA for EDSIVO for the treatment of vEDS. The FDA indicated to us at that time that it expected that the 505(b)(2) NDA for EDSIVO is likely to qualify for priority review. Priority review provides an expedited six-month review cycle after acceptance of the NDA for filing, instead of the traditional ten-month review cycle, for drugs that treat a serious condition and demonstrate the potential to be a significant improvement in safety or effectiveness of the treatment, prevention, or diagnosis of the condition. The FDA determines whether an application will receive priority review at the time the application is accepted for filing. (Emphasis added).

109. The foregoing statements were materially false and misleading because Defendants knew or recklessly disregarded that the FDA did not enter into any such agreement with Defendants that no additional clinical trial would be required for Acer to obtain FDA approval for EDSIVO. By misrepresenting the FDA's communications to Acer regarding the need for further clinical development to obtain FDA approval, Defendants misled investors about the likelihood of and timeline for FDA approval of EDSIVO.

110. Defendants also stated in the 2017 10-K:

> In May 2017, we held a Type C meeting with the FDA to discuss non-clinical and manufacturing data, and proactively identify whether there were any gaps for us to address in advance of a pre-NDA meeting. In our non-clinical data package, we are addressing a potential preclinical gap by conducting in vitro drug-drug interaction studies, which were missing from the Aventis MHRA dossier. We also reached agreement with the FDA regarding Chemistry, Manufacturing and Controls (CMC) specifications. Furthermore, ***the FDA provided us with additional guidance on the expected presentation of the existing clinical data for EDSIVO™ to support the NDA filing***. (Emphasis added).

111. The foregoing statements were materially false and misleading because by reporting to investors that the FDA had provided "guidance" as to how Defendants should "present[ ]" the "existing clinical data for EDSIVO," Defendants led investors to believe that the

Ong Trial data were sufficient to support FDA approval. By omitting to disclose the FDA's communications to Acer regarding the need for further clinical development to obtain FDA approval, Defendants misled investors about the true likelihood of and timeline for FDA approval of EDSIVO.

112. On July 31, 2018, Acer filed with the SEC its Preliminary Prospectus Supplement in connection with a secondary public offering of common stock ("July 31, 2018 Preliminary Prospectus Supplement").[16] In the July 31, 2018 Preliminary Prospectus Supplement, Defendants stated:

> ***In September 2015, we met with the FDA to discuss the existing clinical data for EDSIVO™. At that meeting, the FDA agreed that an additional clinical trial is not likely needed*** and stated that we may submit a 505(b)(2) NDA for EDSIVO™ for the treatment of vEDS. The FDA indicated to us at that time that it expected that the 505(b)(2) NDA for EDSIVO™ is likely to qualify for priority review. Priority review provides an expedited six-month review cycle after acceptance of the NDA for filing, instead of the traditional ten-month review cycle, for drugs that treat a serious condition and demonstrate the potential to be a significant improvement in safety or effectiveness of the treatment, prevention, or diagnosis of the condition. The FDA determines whether an application will receive priority review at the time the application is accepted for filing. (Emphasis added).

113. The foregoing statements were materially false and misleading because Defendants knew or recklessly disregarded that the FDA did not enter into any such agreement with Defendants that no further clinical trial would be required for Acer to obtain FDA approval for EDSIVO. By misrepresenting the FDA's communications to Acer regarding the need for further

[16] On August 1, 2018, Acer filed with the SEC its Prospectus Supplement, which is at least substantially similar, if not virtually identical, to the July 31, 2018 Preliminary Prospectus Supplement. The July 31, 2018 Preliminary Prospectus Supplement and August 1, 2018 Prospectus Supplement formed part of a registration statement signed by Defendants Schelling and Palmin. The language quoted immediately below is identical.

clinical development to obtain FDA approval, Defendants misled investors about the likelihood of and timeline for FDA approval of EDSIVO.

114. In the July 31, 2018 Preliminary Prospectus Supplement, Defendants also stated:

> In May 2017, we held a Type C meeting with the FDA to discuss non-clinical and manufacturing data, and proactively identify whether there were any gaps for us to address in advance of a pre-NDA meeting. In our non-clinical data package, we are addressing a potential preclinical gap by conducting in vitro drug-drug interaction studies, which were missing from the Aventis MHRA dossier. We also reached agreement with the FDA regarding Chemistry, Manufacturing and Controls (CMC) specifications. Furthermore, ***the FDA provided us with additional guidance on the expected presentation of the existing clinical data for EDSIVO™ to support the NDA filing.*** (Emphasis added).

115. The foregoing statements were materially false and misleading because by reporting to investors that the FDA had provided "guidance" as to how Defendants should "present[ ]" the "existing clinical data for EDSIVO," Defendants led investors to believe that the Ong Trial data were sufficient to support FDA approval. By omitting to disclose the FDA's communications to Acer regarding the need for further clinical development to obtain FDA approval, Defendants misled investors about the true likelihood of and timeline for FDA approval of EDSIVO.

LOSS CAUSATION

116. On June 25, 2019, Defendants issued the June 25, 2019 Press Release, which revealed that the FDA had rejected Acer's NDA for EDSIVO. According to the June 25, 2019 Press Release, in the CRL the FDA cited the need for an "adequate and well-controlled trial" evaluating EDSIVO's effectiveness in reducing the risk of clinical events in patients with vEDS. Specifically, the June 25, 2019 Press Release stated, in pertinent part, the following:

> Acer Therapeutics Inc. (Nasdaq: ACER), a pharmaceutical company focused on the acquisition, development and commercialization of therapies for serious rare and life-threatening

> diseases with significant unmet medical needs, today announced it has received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding its New Drug Application (NDA) for EDSIVO™ for the treatment of vascular Ehlers-Danlos syndrome (vEDS). The CRL states that it will be necessary to conduct an adequate and well-controlled trial to determine whether celiprolol reduces the risk of clinical events in patients with vEDS. Acer plans to request a meeting to discuss the FDA's response.
>
> "We remain committed to working closely with the FDA to fully understand its response," said Chris Schelling, CEO and Founder of Acer. "We expect to respond to the FDA in the third quarter of this year."

117. On the above news correcting Defendants' prior misrepresentations and omissions of material fact, the per-share price of Acer common stock fell $15.16, or 78.63%, to close at $4.12 per share on June 25, 2019.

118. As a result of Defendants' wrongful acts and omission, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

ADDITIONAL SCIENTER ALLEGATIONS

Defendants were motivated to make false and misleading statements because Acer needed to raise money to continue as a going concern.

119. By late 2017, Acer had substantial concerns about its ability to continue operations, including its funding of the development of EDSIVO. On November 13, 2017, the Company filed its quarterly report on Form 10-Q for the third quarter of fiscal 2017 ("3Q2017 10-Q"). In the 3Q2017 10-Q, Defendants stated:

> There is substantial doubt about the Company's ability to continue as a going concern within one year after the date that the accompanying financial statements are available to be issued and these financial statements do not include any adjustments relating to the recoverability of recorded asset amounts that might be necessary as a result of the above uncertainty. Based on available resources, the Company believes that its cash and cash equivalents currently

> on hand are sufficient to fund its anticipated operating and capital requirements through the first half of 2018.

120. Also, in the 3Q2017 10-Q, Defendants stated:

> Our current capital resources are not sufficient to fund our planned operations for the next 12 months. We will continue to require substantial additional capital to continue our clinical development and pursuit of regulatory approval activities. Accordingly, we will need to raise substantial additional capital to continue to fund our operations. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our development, regulatory and commercialization efforts. Failure to raise capital as and when needed, on favorable terms or at all, would have a negative impact on our financial condition and our ability to develop and potentially commercialize (if approved) our product candidates. Based on available resources, we believe that our cash and cash equivalents currently on hand are sufficient to fund our anticipated operating and capital requirements through the first half of 2018.

121. In addition, Defendants stated in the 3Q2017 10-Q the following:

> We expect to incur significant expenses and increasing operating losses for at least the next two years as we initiate and continue the clinical development of, seek regulatory approval for, and potentially commercialize (if approved) our product candidates and add personnel necessary to operate as a public company with an advanced clinical pipeline of product candidates. In addition, operating as a publicly-traded company involves the hiring of additional financial and other personnel, upgrading financial information systems, and incurring costs associated with operating as a public company. We expect that our operating losses will fluctuate significantly from quarter-to-quarter and year-to-year due to the timing of clinical development programs, efforts to achieve regulatory approval and planning for potential commercialization (if approved) of our product candidates.

122. The 3Q2017 10-Q further stated "***Our auditors have expressed doubt about our ability to continue as a going concern***" and "[b]ecause we have been issued an opinion by our independent registered public accounting firm that substantial doubt exists as to whether we can continue as a going concern, it may be more difficult for us to attract investors." (emphasis in original).

123. Additionally, the 3Q2017 10-Q stated that "[a]s of September 30, 2017, we had approximately $8.4 million in cash and cash equivalents."

124. On December 11, 2017, Acer issued a press release ("December 11, 2017 Press Release") announcing the proposed underwritten public offering of common stock. In the December 11, 2017 Press Release, Defendants stated that the Company "intends to use the net proceeds from this offering to fund its research and development efforts, to seek regulatory approval for EDSIVO™, to invest in pre-commercial activities for EDSIVO™ and for general corporate purposes, including working capital and other general and administrative purposes."

125. In the preliminary and final prospectus supplement for that offering, Defendants made the false and misleading statement that "the FDA agreed that additional clinical development is not needed" for EDSIVO.

126. On December 14, 2017, Acer issued a press release ("December 14, 2017 Press Release") announcing the pricing of its underwritten public offering of common stock. In the December 14, 2017 Press Release, Defendants reported "the closing of the previously announced underwritten public offering of 916,667 shares of its common stock at a price to the public of $12.00 per share." Defendants also stated in the December 14, 2017 Press Release that "[t]he gross proceeds to Acer from this offering were $11.0 million, before deducting the underwriting discount and other estimated offering expenses," and that "Acer intends to use the net proceeds from this offering to fund its research and development efforts, to seek regulatory approval for EDSIVO™, to invest in pre-commercial activities for EDSIVO and for general corporate purposes, including working capital and other general and administrative purposes."

127. On December 27, 2017, Acer issued a press release ("December 27, 2017 Press Release") announcing that the underwriters had "partially exercised their over-allotment option by

the purchase of an additional 130,000 shares at a price to the public of $12.00 per share, resulting in additional gross proceeds of $1.56 million, before deducting underwriting discounts and commissions and other offering expenses payable by Acer." "After giving effect to the partial exercise of the over-allotment option," according to the December 27, 2017 Press Release, "the total number of shares sold by Acer in the offering increased to 1,046,667 shares and the total gross proceeds increased to $12.56 million." Defendants added: "Acer intends to use the net proceeds from this offering to fund its research and development efforts, to seek regulatory approval for EDSIVO, to invest in pre-commercial activities for EDSIVO and for general corporate purposes, including working capital and other general and administrative purposes."

128. In the 2017 10-K, Defendants stated:

> On December 14, 2017, the Company closed on an underwritten public offering of its common stock of 916,667 shares at a price of $12.00 per share. The gross proceeds were $11.0 million, before deducting the underwriting discount and other estimated offering expenses. Subsequently, on December 27, 2017, the Company sold an additional 130,000 shares in connection with the over-allotment option granted to the underwriters, for an additional $1.6 million of gross proceeds, before deducting the underwriting discount. The total amount of underwriting discount and other offering costs deducted from gross proceeds was $1.1 million.

129. In addition, the 2017 10-K stated that "[a]s of December 31, 2017, we had approximately $15.6 million in cash and cash equivalents."

130. On May 14, 2018, the Company filed its quarterly report on Form 10-Q for the First quarter of fiscal 2017 ("3Q2017 10-Q"):

> Based on available resources, the Company believes that its cash and cash equivalents currently on hand are sufficient to fund its anticipated operating and capital requirements through the end of 2018. ***There is substantial doubt about the Company's ability to continue as a going concern within one year after the date that the accompanying financial statements are issued.***

(emphasis added).

131. On May 31, 2018 Acer issued a press release ("May 31, 2018 Press Release") announcing its intention to offer and sell shares of its common stock in an underwritten public offering. According to the May 31, 2018 Press Release:

> Acer intends to use the net proceeds from this offering to fund its research and development efforts, to seek regulatory approval for EDSIVO, to invest in pre-commercial activities for EDSIVO, to advance development of ACER-001, to acquire or in-license product candidates, and for general corporate purposes, including working capital and other general and administrative purposes.

132. On August 1, 2018, Acer issued a press release ("August 1, 2018 Press Release") announcing the pricing of its underwritten public offering. In the August 1, 2018 Press Release, Defendants announced "the pricing of its underwritten public offering of 2,222,222 shares of its common stock at a public offering price of $18.00 per share." "The gross proceeds from the offering, before deducting underwriting discounts and commissions and estimated offering expenses payable by Acer," according to the August 1, 2018 Press Release, "are expected to be approximately $40.0 million." "In addition," Defendants stated, "Acer granted the underwriters in the offering a 30-day option to purchase up to 333,333 additional shares of common stock at the public offering price, less the underwriting discounts and commissions." The August 1, 2018 Press Release further stated:

> Acer intends to use the net proceeds from this offering to fund its research and development efforts, to seek regulatory approval for EDSIVO, to invest in pre-commercial activities for EDSIVO, to advance development of ACER-001, to acquire or in-license product candidates, and for general corporate purposes, including working capital and other general and administrative purposes.

133. In the preliminary and final prospectus supplement for that offering, Defendants made the false and misleading statement that "the FDA agreed that an additional clinical trial is not likely needed" for EDSIVO.

134. On August 3, 2018, the Company issued a press release ("August 3, 2018 Press Release") announcing the closing of its underwritten public offering. The August 3, 2018 Press Release reported that "[t]he gross proceeds to Acer from this offering are approximately $46.0 million, before deducting underwriting discounts and commissions and estimated offering expenses." The offering consisted of "2,555,555 shares of its common stock, including 333,333 shares sold pursuant to the underwriters' full exercise of their option to purchase additional shares to cover over-allotments, at a public offering price of $18.00 per share." Defendants stated that the Company:

> intends to use the net proceeds from this offering to fund its research and development efforts, to seek regulatory approval for EDSIVO, to invest in pre-commercial activities for EDSIVO, to advance development of ACER-001, to acquire or in-license product candidates, and for general corporate purposes, including working capital and other general and administrative purposes.

135. On March 7, 2019, Acer filed with the SEC its annual report on Form 10-K for the fiscal year ended December 31, 2018 ("2018 10-K"). In the 2018 10-K, Defendants stated:

> On August 3, 2018, we completed an underwritten public offering of 2,555,555 shares of common stock at a public offering price of $18.00 per share. We received aggregate net proceeds of approximately $42.7 million, after deducting underwriting discounts, commissions and offering-related expenses of approximately $3.3 million. As of December 31, 2018, we had approximately $41.7 million in cash and cash equivalents.

136. Given that Acer desperately needed cash to continue as a going concern, the Company and Defendants Schelling and Palmin, as President and CEO and CFO, respectively, were highly motivated to misrepresent the FDA's statements about EDSIVO. Furthermore, in light of the Company's precarious situation, any admission that an additional clinical trial for EDSIVO was necessary would have been catastrophic for the Company given the cost and time necessary for the trial as described in Paragraph 93.

Defendants Schelling and Palmin behaved intentionally or recklessly when they approved Acer's SEC filings.

137. Given the importance of EDSIVO to Acer, it is inconceivable that as President and CEO and CFO, respectively, that Defendants Schelling and Palmin would not have been well versed about the FDA's communications with Acer about the drug. They certainly would have been aware that the FDA had not agreed "that additional clinical development is not needed" or that "an additional clinical trial is not likely needed" for EDSIVO at the time Acer made those statements. At minimum, they would have been aware that there was not such agreement long before the FDA issued its CRL for EDSIVO given the many meetings of Acer's top officials with the FDA. Accordingly, they would have had the duty to correct or update those statements.

138. Each of the Individual Defendants was provided with copies of Company's SEC filings that contained the misleading statements alleged herein before their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected. Defendants Schelling and Palmin were, at minimum, reckless when they authorized the issuance of the December 11, 2017 Preliminary Prospectus Supplement, December 12, 2017 Prospectus Supplement, July 31, 2018 Preliminary Prospectus Supplement, and August 1, 2018 Prospectus Supplement as part of the registration statement they signed. They were also, at minimum, reckless when they signed the 2017 10-K and the required SOX certifications that accompanied it. The SOX certifications for the 2017 10-K that Defendants Schelling and Palmin signed stated that "based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report."

139. It is also clear that Defendants intentionally mislead investors based on the revision of their description of FDA's purported agreement with Acer at the September 2015 meeting, as described in Paragraph 48-53.

There is a strong inference Acer acted with Scienter

140. Each of the Individual Defendants was a high-ranking management-level employee. The scienter of each of the Individual Defendants and of all other management-level employees of Acer, including each high-ranking officer or director, is imputable to the Company. The knowledge of each of these individuals should therefore be imputed to Acer for the purposes of assessing corporate scienter.

141. Even aside from the scienter of the Individual Defendants, the facts alleged herein raise a strong inference of corporate scienter as to Acer as an entity. Corporate scienter may be alleged independent of individual defendants where a statement is made or approved by a corporate official sufficiently knowledgeable about the company to know the statement was false or misleading. Given the importance of EDSIVO to Acer, the false and misleading statements alleged in this complaint would necessarily have required the approval of a corporate officer with knowledge that they were false and misleading.

.PLAINTIFF'S CLASS ACTION ALLEGATIONS

142. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Acer securities during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosure. Excluded from the Class are Defendants, the officers and directors of Acer, members of the Individual Defendants' immediate families and their

legal representatives, heirs, successors or assigns and any entity in which the Individual Defendants have or had a controlling interest.

143. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Acer securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class.

144. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

145. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

146. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

a. whether the federal securities laws were violated by Defendants' acts as alleged herein;

b. whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Acer;

c. whether the Individual Defendants caused Acer to issue false and misleading financial statements during the Class Period;

d. whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;

e. whether the prices of Acer securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and

f. whether the members of the Class have sustained damages and, if so, what the proper measure of damages is.

147. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

148. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

a. Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

b. the omissions and misrepresentations were material;

c. the Company's securities are traded in efficient markets;

d. the Company's securities were liquid and traded with moderate to heavy volume during the Class Period;

e. the Company traded on the NASDAQ, and was covered by multiple analysts;

f. the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; Plaintiff and members of the Class purchased and/or sold the Company's securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts; and

g. unexpected material news about the Company was rapidly reflected in and incorporated into the Company's stock price during the Class Period.

149. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

150. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

COUNT I

Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Against All Defendants

151. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

152. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

153. During the Class Period, the Company and the Individual Defendants, individually and in concert, directly or indirectly, disseminated or approved the false statements specified above, which they knew or deliberately disregarded were misleading in that they contained

misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

154. The Company and the Individual Defendants acted with scienter in that they knew that the public documents and statements issued or disseminated in the name of the Company were materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated, or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the securities laws. These defendants by virtue of their receipt of information reflecting the true facts of the Company, their control over, and/or receipt and/or modification of the Company's allegedly materially misleading statements, and/or their associations with the Company which made them privy to confidential proprietary information concerning the Company, participated in the fraudulent scheme alleged herein.

155. Individual Defendants, who are the senior officers and/or directors of the Company, had actual knowledge of the material omissions and/or the falsity of the material statements set forth above, and intended to deceive Plaintiff and the other members of the Class, or, in the alternative, acted with reckless disregard for the truth when they failed to ascertain and disclose the true facts in the statements made by them or other personnel of the Company to members of the investing public, including Plaintiff and the Class.

156. As a result of the foregoing, the market price of the Company's securities was artificially inflated during the Class Period. In ignorance of the falsity of the Company's and the Individual Defendants' statements, Plaintiff and the other members of the Class relied on the statements described above and/or the integrity of the market price of the Company's securities during the Class Period in purchasing the Company's securities at prices that were artificially

inflated as a result of the Company's and the Individual Defendants' false and misleading statements.

157. Had Plaintiff and the other members of the Class been aware that the market price of the Company's securities had been artificially and falsely inflated by the Company's and the Individual Defendants' misleading statements and by the material adverse information which the Company and the Individual Defendants did not disclose, they would not have purchased the Company's securities at the artificially inflated prices that they did, or at all.

158. As a result of the wrongful conduct alleged herein, Plaintiff and other members of the Class have suffered damages in an amount to be established at trial.

159. By reason of the foregoing, the Company and the Individual Defendants have violated Section 10(b) of the 1934 Act and Rule 10b-5 promulgated thereunder and are liable to the Plaintiff and the other members of the Class for substantial damages which they suffered in connection with their purchases of the Company's securities during the Class Period.

COUNT II

Violations of Section 20(a) of the Exchange Act Against the Individual Defendants

160. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

161. During the Class Period, the Individual Defendants participated in the operation and management of the Company, and conducted and participated, directly and indirectly, in the conduct of the Company's business affairs. Because of their senior positions, they knew the adverse non-public information regarding the Company's business practices.

162. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to the

Company's financial condition and results of operations, and to correct promptly any public statements issued by the Company which had become materially false or misleading.

163. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which the Company disseminated in the marketplace during the Class Period. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause the Company to engage in the wrongful acts complained of herein. The Individual Defendants, therefore, were "controlling persons" of the Company within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of the Company's securities.

164. Each of the Individual Defendants, therefore, acted as a controlling person of the Company. By reason of their senior management positions and/or being directors of the Company, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, the Company to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of the Company and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

165. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by the Company.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

Dated: February 28, 2020

THE ROSEN LAW FIRM, P.A.

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Lead Counsel for Plaintiff and the Putative Class

CERTIFICATE OF SERVICE

I hereby certify that on February 28, 2020, I electronically filed the foregoing ***Second Amended Class Action Complaint for Violation of the Federal Securities Laws*** with the Clerk of Court using the CM/ECF system, which will send notification of such to all CM/ECF participants.

THE ROSEN LAW FIRM, P.A.

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